


WHAT IS CLAIMED IS:

1  1. A hand-held, portable, aerosol drug delivery system, comprising:
2 a disposable container containing a drug formulation;
3 an aerosol generator for aerosolizing the drug formulation;
4 a prevention device which prevents access to the drug formulation when in
5 an inactive state and which permits access to the drug formulation when in an activated
6 state.

1 2. A system as in claim 1, wherein the prevention device comprises
2 an electronic lockout device having a lockout element that is positioned in a dose
3 preventing position when in the inactive state, and is movable to a dosing permitting
4 position when electric current is supplied to place the lockout device in the activated
5 state.

1 3. A system as in claim 2, wherein the lockout device further
2 comprises circuitry for supplying electrical current to move the lockout element to the
3 dose permitting position when the lockout device is in the activated state.

1 4. A system as in claim 2, wherein the lockout device further
2 comprises a controller having an associated memory for storing a dosing condition, and
3 wherein the controller is configured to send a signal to place the lockout device in the
4 activated state only after the dosing condition has been satisfied.

1 5. A system as in claim 2, wherein the container comprises a canister,
2 and wherein the aerosol generator comprises a metering valve and an actuator operably
3 coupled to the canister.

1 6. A system as in claim 5, further comprising a housing, wherein the
2 canister is reciprocally held within at least a portion of the housing between a home
3 position and a dosing position where the actuator is engaged to open the metering valve
4 and to permit the escape of a metered amount of the drug formulation from the canister.

1 7. A system as in claim 6, wherein the lockout element is positioned
2 to prevent engagement of the actuator when in the dose preventing position to thereby
3 prevent opening of the metering valve.

1 8. A system as in claim 7, wherein the lockout element has a distal
2 end that is engageable with the canister to prevent substantial displacement of the canister
3 into the housing when the lockout element is in the dose preventing position.

1 9. A system as in claim 8, wherein upon placement of the preventing
2 device into the activated state, the distal end of the lockout element is retracted to permit
3 displacement of the canister into the housing and to permit engagement of the actuator to
4 open the metering valve.

1 10. A system as in claim 7, wherein the canister is movable within the
2 housing when the preventing device is in the inactive state, and further comprising a stop
3 that is reciprocally disposed within the housing below the actuator, and wherein the
4 lockout element has a distal end that is engageable with the stop when in the activated
5 state to prevent movement of the stop within the housing such that displacement of the
6 canister engages the actuator with the stop to permit dispensing of the metered drug
7 formulation when the preventing device is in the activated state.

1 11. A system as in claim 1, further comprising a high pressure gas
2 source to assist in aerosolizing the drug formulation when the preventing device is in the
3 activated state.

1 12. A system as in claim 1, further comprising a dose counter disposed
2 to count the number of doses of the drug formulation dispensed from the container.

1 13. A system as in claim 12, wherein the container is reciprocatably
2 disposed within a housing, and wherein the dose counter comprises a dose counting
3 circuit positioned to sense when the container has been reciprocated within the housing.

1 14. A system as in claim 13, wherein the dose counter further
2 comprises a display for indicating if the container contains an amount of drug
3 formulation.

1 15. A system as in claim 5, further comprising a nozzle operable
2 coupled to the canister, and wherein the housing further includes a mouthpiece disposed
3 to receive the drug formulation from the nozzle.

1 16. A system as in claim 15, wherein the mouthpiece has a first end
2 and a second end, and wherein the nozzle is positionable within an opening adjacent the
3 first end of the mouthpiece to permit the aerosolized drug formulation to be delivered to a
4 patient upon inhalation through the second end of the mouthpiece.

1 17. A method for administering a drug formulation, the method
2 comprising:
3 providing a container having an amount of a drug formulation;
4 preventing the transfer of the drug formulation from the container with an
5 electronic lockout device when the lockout device is in an inactive state; and
6 supplying electrical current to the lockout device to place the lockout
7 device in an active state, thereby permitting the transfer of the drug formulation from the
8 container.

1 18. A method as in claim 17, wherein the electronic lockout device
2 comprises a lockout element that is positioned in a dose preventing position when in the
3 inactive state, and further comprising moving the lockout element to a dosing permitting
4 position when electric current is supplied to place the lockout device in the activated
5 state.

1 19. A method as in claim 18, wherein the container comprises a
2 canister having a metering valve and an actuator, wherein the canister is reciprocatably
3 held within a housing between a home position and a dosing position, and further
4 comprising depressing the canister into the housing to the dosing position to engage the
5 actuator and to release a metered amount of the drug formulation when the lockout device
6 is in the active state.

1 20. A method as in claim 19, further comprising preventing
2 engagement of the actuator when the lockout element is in the dose preventing position.

1 21. A method as in claim 20, further comprising engaging the canister
2 with the lockout element to prevent movement of the canister to the dispensing position
3 when the lockout element is in the dose preventing position.

1 22. A method as in claim 21, further comprising disengaging the
2 lockout element from the canister to permit movement of the canister to the dispensing
3 position upon supply of the electrical current.

1 23. A method as in claim 20, further comprising engaging the lockout
2 element with a stop that is positioned below the actuator upon supply of the electrical
3 current, and further comprising depressing the canister into the housing to engage the
4 actuator with the stop.

1 24. A method as in claim 18, further comprising stopping the supply of
2 the electric current to the lockout device after the drug formulation has been transferred
3 from the container.

1 25. A method as in claim 24, further comprising supplying electric
2 current to the lockout device to permit another dosing only after a certain dosing
3 conditions have been satisfied.

1 26. A method as in claim 25, further comprising counting the number
2 doses transferred from the container.

1 27. A method as in claim 26, further comprising displaying whether
2 the container contains an amount of drug formulation based on the number of counts.

1 28. A hand-held, portable, aerosol drug delivery system, comprising:
2 a housing having a mouthpiece;
3 a canister that is movable within the housing when manually depressed
4 into the housing, the canister having a metering valve that is operable to release a metered
5 amount of a drug formulation from the canister; and

6 a control system to control opening of the valve such that the valve is only
7 opened when a force is manually applied to depress the canister into the housing and
8 when a dosing condition has been satisfied.

1 29. A system as in claim 28, wherein the control system comprises a
2 controller and a locking mechanism, wherein the controller is configured to send a signal
3 to the locking mechanism to permit opening of the valve once the dosing condition has
4 been satisfied.

40050 " 504350

1 30. A system as in claim 29, wherein the dosing condition is the
2 passage of a certain amount of time between dosings, and further comprising an
3 electronic clock coupled to the controller to measure the passage of time between dosings.

1 31. A system as in claim 28, wherein the locking mechanism is
2 normally in a dose preventing position and is movable to a dosing position when
3 electrical current is supplied to the locking mechanism to permit opening of the valve
4 when the canister is depressed.

1 32. A system as in claim 28, wherein the locking mechanism includes a
2 locking element that engages the canister to prevent depression of the canister into the
3 housing when in the dose preventing position.

1 33. A system as in claim 28, wherein the canister includes an actuator,
2 and wherein the locking mechanism includes a locking element that engages a stop that in
3 turn engages the actuator when in the dose permitting position and when the canister is
4 depressed into the housing.

1 34. A method for administering a nicotine formulation for smoking
2 cessation therapy, the method comprising:
3 providing an amount of a nicotine formulation;
4 preventing the aerosolization of the nicotine formulation with a lockout
5 device when the lockout device is in an inactive state;
6 supplying electric current to the lockout device to place the lockout device
7 in an active state; and
8 aerosolizing the nicotine formulation.

1 35. A method as in claim 34, further comprising controlling when
2 electric current may be supplied to the lockout device based on a specified dosing
3 schedule.

1 36. A system as in claim 1, wherein the drug formulation comprises
2 nicotine.
3
4